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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/829,251	04/09/2001	Laura C. Simmons	A-63487-3/RFT/JJD	1050
7590 02/13/2004			EXAMINER	
Janet E. Hasak Genentech, Inc. 1 DNA Way South San Francisco, CA 94080-4990			KATCHEVES, KONSTANTINA T	
			ART UNIT	PAPER NUMBER
			1636	
DATE MAILED: 02/13/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/829,251	Applicant(s) SIMMONS ET AL.	
	Examiner Konstantina Katcheves	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5,6,8-14 and 16-26 is/are pending in the application.
- 4a) Of the above claim(s) 10,12-14,16-23 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5,6,8,9,11,24 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/14/03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 5, 6, 8-14 and 16-26 are pending in the present application. Claims 10, 12-14, 16-23 and 26 are withdrawn from consideration. Consequently, claims 5, 6, 8, 9, 11, 24 and 25 are currently under consideration. This Office action is in response to Applicant's amendment and remarks 6 November 2003.

Response to Amendment

The rejection of claims 5, 6, 8, 9, 11, 24 and 25 under 35 U.S.C. 112, second paragraph have been withdrawn in view of Applicant's amendments filed 6 November 2003.

The rejection of claims 5, 8, 9, 11, 24 and 25 under 35 U.S.C. 102(b) have been withdrawn in view of Applicant's arguments filed 6 November 2003.

The rejection of claims 5, 6, 8, 9, 11, 24 and 25 under 35 U.S.C. 103(a) have been withdrawn in view of Applicant's arguments filed 6 November 2003.

New Grounds of Rejections

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 5, 6, 8, 9, 11, 24 and 25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,840,523 ('523 Patent) and over claims 1-4 of U.S. Patent No. 6,242,177 ('177 Patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are obvious variation of the claims of the '523 Patent and the '177 Patent.

The present claims are drawn to a method of secreting a heterologous polypeptide of interest comprising a translation initiation region variant having lower translational strength than wild type translational initiation regions. The '523 Patent also discloses in claim 1 a method of secreting a heterologous polypeptide comprising a translation initiation region variant having lower translational strength than wild type translational initiation regions. Therefore, claim 1 of the '523 Patent falls entirely within the scope of the present claims, or in other words, the present claims are anticipated by the claims of the '523 Patent.

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Although Applicant does not claim a method of optimizing secretion, Applicant claims a method of secreting a polypeptide comprising a translation initiation region variant having less translational strength than wildtype like the method steps of the '177 Patent. Because the claims of the '177 Patent, like those of the '523 Patent described above, are narrower in scope than the present claims, the present claims are generic to the claims of the '177 patent. Thus, the present claims are anticipated by the claims of the '177 Patent.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5, 6, 8, 9, 11, 24 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description requirement is established by 35 U.S.C. 112, first paragraph which states that the: "*specification* shall contain a written description of the invention. . .[emphasis added]." The written description requirement has been well established and characterized in the case law. A specification must convey to one of skill in the art that "as of the filing date sought, [the inventor] was in possession of the invention." See *Vas Cath v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show

that he is in “possession” of the invention claimed by describing the invention with all of its claimed limitations “by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.” See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

The instant claims are drawn transcription initiation region variants wherein the translational strength of said variants is less than the translational strength of a wild-type translational initiation region. This genus of transcription initiation region variants encompasses a wide array of molecules for which the specification lacks adequate written description.

Applicant’s specification discloses translational initiation regions include the signal sequences STII, OmpA, PheE, LamB, MBP and PhoA. However, the specification fails to disclose variants of the translational initiation regions which have lower translational strength than their wild-type counterparts. The specification fails to disclose the variants or modifications of the claimed translational initiation regions having lower translational strength than wild type and does not provide any teachings or guidance as to how the structures of these translation initiation region variants relate to their function. The specification also fails to disclose any common features in the claimed translation initiation region variants that would result in lower translational strength. Thus, the specification does not describe the complete structure of a representative number of species of the claimed invention. Absent of such teachings and guidance as to the structure-function relationship of these variants, the specification does not describe the claimed translational initiation region variants in such full, clear, concise and exact terms such that one of skill in the art would reasonably conclude that Applicant had possession of this subject matter at the time of filing of the present application.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (571) 272-0768. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday 7:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konstantina Katcheves
9 February 2004


JAMES KETTER
PRIMARY EXAMINER